REMARKS

Status of the Claims

Claims 5-27 are currently pending. Claims 1-4 and 28-30 were drawn to non-elected inventions and stand cancelled. Claim 5 has been amended.

Applicant filed an Amendment After Final Rejection on July 6, 2009. The Examiner responded to the Amendment After Final Rejection in an Advisory Action mailed July 21, 2009, indicating that the proposed amendments were not entered. Accordingly, the amendments are presented here again.

Support for the amendments to claim 5 can be found throughout the specification as filed, *inter alia*, at paragraphs **[0054]**, **[0085]**, **[0089]**, **[0107] and [0113]**. The scope of the claim is not limited by this amendment. The amendment merely serves to clarify that the liquid cell culture medium present in the media reservoir is capable of diluting the cryoprotectant from the cryoprotectant containing medium, wherein thawing of the cryoprotectant containing medium and the liquid cell culture medium combines the cells, the cryoprotectant containing medium, and the liquid cell culture medium to provide a medium to culture the cells. This dilution thus occurs after thawing, in contrast to the cited art teaching cryopreservation of cells. The cryopreservation devices in the prior art are not capable of culturing cells, unlike the presently claimed devices. In addition, the claim specifies that the media reservoir is distinct from the cell reservoir.

No new matter has been added. Upon entry of the amendments, claims 5-27 will be pending. Entry of the amendment and reconsideration of the claims on the merits is respectfully requested.

With respect to all amended claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any

presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Final Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejection Under 35 U.S.C. § 102

Claims 5-9, 12-16, 18, 20, 22, 25 and 26 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Livesey (U.S. Pat. No. 4,865,871, hereinafter "Livesey").

The Office alleged that Livesey "discloses a kit comprising a self-contained cell culture vessel that includes a sample holder (Figure 4:100) for accommodating cell reservoirs (Figure 4:111) and media reservoirs (Figure 4:111). This is disclosed in column 17, lines 6-17. Column 15, lines 3-21 state that the sample holder is positioned within a gas reservoir (Figure 4:90) capable of being used to hold a dry nitrogen gas." (OA at pages 2-3). Applicants traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Livesey does not teach each and every element as set forth in claim 5.

Claim 5 is directed to a self-contained cell culture vessel comprising a cell reservoir, a media reservoir distinct from the cell reservoir, and a gas reservoir; cells and a cryoprotectant containing medium disposed in said cell reservoir; a liquid cell culture medium disposed in said media reservoir in an amount capable of diluting the cryoprotectant to a volume suitable for cell growth, wherein thawing of the cryoprotectant containing medium and the liquid cell culture

medium combines the cells, the cryoprotectant containing medium, and the liquid cell culture medium to provide a medium to culture the cells; and gas disposed in the gas reservoir.

As discussed in the previous responses, which are incorporated by reference herein in their entirety, Livesey discloses an apparatus for the cryopreparation of tissue samples. The tissue sample can be treated with a cryoprotectant prior to vitrification in the disclosed apparatus. After vitrification, the sample is transferred via a specimen transport and fed to a specimen holder (also called a sample holder) that is maintained in a temperature-controlled container. (Col. 9, lines 33-36). The sample is then dehydrated. (Col. 9, line 49 – Col. 10, line 66). The tissue may then be further treated, i.e., by polymerization with resin, or is stored under inert conditions for later rehydration. (Col. 11, line 34 – Col. 12, line 12). Livesey describes the apparatus used for such processes in Columns 12 – 18.

Applicants note that the claims are directed to a self-contained cell culture vessel comprising a cell reservoir, *a media reservoir distinct from the cell reservoir*, and a gas reservoir; cells and a cryoprotectant containing medium disposed in said cell reservoir; *a liquid cell culture medium disposed in said media reservoir in an amount capable of diluting the cryoprotectant to a volume suitable for cell growth, wherein thawing of the cryoprotectant containing medium and the liquid cell culture medium combines the cells, the cryoprotectant containing medium, and the liquid cell culture medium to provide a medium to culture the cells*; and gas disposed in the gas reservoir.

The claims explicitly require the presence of a media reservoir distinct from the cell reservoir. Livesey does not teach or suggest a media reservoir that is distinct from the cell reservoir. The Office appears to agree with this analysis, since it stated the following in response to Applicants' previous Amendment:

> It is agreed that the Livesey apparatus is used to cryoprepare a biological tissue for storage and subsequent transplantation. However, prior to vitrification and freezing, a tissue sample is mixed with a cryoprotectant for over a period of hours. This is disclosed in column 8, lines 14-24. Column 8, lines 39-45 specifically states that the cryoprotectants are applied to a tissue sample in the form of a cell culture. Accordingly, it is understood that reservoirs (Figure 4;111) function as cell reservoirs

and media reservoirs because they accommodate both cells and culture fluids. (OA at page 11, emphasis added).

In the Office's analysis, Livesey's **111** reservoirs are both cell reservoirs and media reservoirs. The claim requires that there be a cell reservoir that is distinct from the media reservoir. Applicants made this argument in the response filed July 6, 2009, but the Office ignored this aspect of the response. Accordingly, Livesey does not provide both a cell reservoir and a distinct media reservoir.

Livesey also does not describe that the media reservoir contains liquid cell culture medium in an amount capable of diluting the cryoprotectant to a volume suitable for cell growth, wherein thawing of the cryoprotectant containing medium and the liquid cell culture medium combines the cells, the cryoprotectant containing medium, and the liquid cell culture medium to provide a medium to culture the cells.

Livesey describes part **111** of Figure 4 as a well in the sample holder, which creates "tissue reservoirs," such that "the cryoprepared tissue samples are individually inserted into tissue reservoirs **111** with prechilled forceps as previously disclosed." (Col. 17, lines 11-17). Contrary to the Office's assertions, this tissue reservoir **111** is not analogous to a media reservoir, but is instead a *cell reservoir.* The Office notes that "the claims do not require cell growth, but rather only conditions suitable for cell growth. Prior to vitrification/supercooling, the culture sample is suitable for cell growth." (OA at page 11). However, this analysis ignores the claim language stating that the liquid cell culture medium from the media reservoir dilutes the cryoprotectant to a volume suitable for cell growth after thawing (c.f. "wherein thawing of the cryoprotectant containing medium and the liquid cell culture medium combines the cells, the cryoprotectant containing medium, and the liquid cell culture medium to provide a medium to culture the cells.") Accordingly, the claims require conditions suitable for cell growth after freezing of the cells and cryoprotectant containing medium.

Livesey only teaches that the cell reservoir contains the cells and cryoprotectant containing medium prior to vitrification. (Col. 17:14-17). Livesey does not teach that the apparatus

contains a separate liquid cell culture medium that upon thawing of the cryoprotectant containing medium and the liquid cell culture medium combines the cells, the cryoprotectant containing medium, and the liquid cell culture medium to provide a medium to culture the cells. In fact, Livesey only makes one mention of rehydrating the cryopreserved tissue. Col. 12:9-12 states: "the sample, cryoprotected or noncryoprotected can be dried without resin embedment but rather stored under inert conditions for later rehydration." Livesey only discusses rehydration of the cryopreserved tissue, but not mixing the cryopreserved cells with a liquid cell culture medium to dilute the cryoprotectant containing medium to a volume suitable for cell growth upon thawing of the cryoprotectant containing medium and the liquid cell culture medium. There is no motivation to include cell culture medium in the tissue reservoirs of Livesey since this would negate the efficacy of the cryopreservation process by decreasing the concentration of the cryoprotectant. There is also nothing in Livesey to indicate that the cryopreserved cells from the tissue reservoirs may be cultured in Livesey's apparatus without the addition of additional cell culture medium.

Livesey does not describe a self-contained apparatus for *culturing* cells (i.e., a "cell culture vessel") as presently claimed, but instead only describes an apparatus for *cryopreserving* cells. In the Advisory Action, the Examiner asserted that "the apparatus of Livesey is fully capable of accommodating a cell culture." The claims however require more than just accommodating a cell culture prior to vitrification and freezing. The claims require cells "a liquid cell culture medium disposed in said media reservoir in an amount capable of diluting the cryoprotectant to a volume suitable for cell growth, wherein thawing of the cryoprotectant containing medium and the liquid cell culture medium combines the cells, the cryoprotectant containing medium, and the liquid cell culture medium to provide a medium to culture the cells." As discussed above, Livesey does not provide these elements.

Furthermore, Livesey does not provide a self-contained apparatus. In the Advisory Action, the Examiner asserted that Applicants did not provide any definition for the term "self-contained" and dismissed this argument. Applicants disagree. The term "self-contained" is used and defined in the specification in at least the following paragraphs:

[0006] Conventional cell culture cannot be performed in the absence of a cell culture facility staffed by well-trained and experienced personnel. In addition, conventional methods require removal of a cryoprotectant from cryopreserved cells upon cell revival. This removal of cryoprotectant (e.g., DMSO, glycerol) from cryopreserved cells involve multiple steps and is usually performed by an experienced personnel. As soon as cryopreserved cells are thawed 37 degree C., they are carefully transferred drop wise into a 10 ml centrifuge tube containing Hanks balanced salt solution or phosphate buffered saline. This gradual dilution process is particularly important when DMSO is used as the cryoprotectant, with which sudden dilution can cause severe osmotic damage and reduce cell survival. The 10 ml tube containing cells is centrifuged at 230 g for 4:30 minutes. The DMSO in the supernatant is aspirated and the cells are recovered and transferred to the cell culture flask in the presence of prewarmed growth medium which is conventionally prewarmed at 37 degree C. for 15 minutes prior to cell culture. The cell culture flask is kept at 37 degree C. in a CO_2 incubator, and cell growth and viability are observed. Therefore, it would be useful to the industry to have a system for performing cell culture that does not require well-trained and experienced personnel.

[0007] Further, it would be advantageous to perform cell cultures without the need to remove cryoprotectant upon cell revival. Therefore, due to the enormous applicability and utility of cell culture in biology, it is desirable to have a self-contained system capable of performing cell culture without human manipulation. The present invention addresses these needs by providing a completely self-contained cell culture system that can be stored for extended periods of time. When required, this system may be thawed and incubated at the desired temperature to carry out cell culture without the need to remove the cryoprotectant.

[0071] Thus, in a preferred embodiment, the present invention is directed to a completely self-contained cell culture system wherein a cell culture may be viably stored frozen for extended periods then incubated and grown when required utilizing only constituents within the self-contained system, and to an apparatus and method whereby this may be accomplished.

[0072] One aspect of the present invention provides an apparatus and method wherein a viable cell culture may be stored frozen, thawed, incubated and grown in a single vessel wherein the cell culture, media and atmosphere necessary thereto are within a completely self-contained device.

[0073] Another aspect of the present invention provides an apparatus and method wherein a cell culture may be stored frozen, thawed, incubated and grown in a self-contained system without the addition of any cell culture, media, atmosphere or other constituent or component from outside the system.

A self-contained cell culture system is thus one where a cell culture is stored frozen, thawed, incubated and grown without the addition of any cell culture, media, atmosphere or other constituent or component from outside the system. Livesey explicitly describes adding and removing cells and media from media reservoir (Figure 4: 111)and sample reservoirs (Figure 4: 111) on sample holder (Figure 4:100) before, during, and after cryopreservation. This is contrary to the definition provided above, where the cell culture is stored frozen, thawed, incubated and grown without the addition of any cell culture, or media from outside the system. Livesey describes freezing cells for further use, at which time they are removed from Livesey's apparatus and cultured using conventional tissue culture methods. Livesey's apparatus is thus not self-contained.

Since Livesey does not teach every limitation of the claims, it does not anticipate the pending claims. Applicants respectfully request that the rejection of claims 5-9, 12-16, 18, 20, 22, 25 and 26 under 35 U.S.C. § 102 be withdrawn.

Rejection Under 35 U.S.C. § 103

Rajotte in view of Wilson

Claims 5-10, 13, 15-18, 20, 22 and 25-27 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Rajotte (US 5863715) in view of Wilson (US 5693537).

With respect to Rajotte, the Office asserted that:

> Rajotte discloses a kit comprising a self-contained cell culture vessel comprising a cell reservoir and a media reservoir in the form of detachable pouches (Figure 6:3a) located above an internal chamber (Figure 6:4). Rajotte teaches in column 4, lines 20-60 that cells, DMSO cryoprotectant, and cell culture media are retained within the upper portions. Rajotte, however, does not indicate that a gas reservoir is provided.

The Office acknowledges that Rajotte differs from the instant claims in failing to teach a gas reservoir.

The Office asserted that Wilson teaches "a tissue flask for cell culture that comprises a culture chamber (Figure 5:40) bounded on one side by a gas permeable membrane (Figure 5:120) in communication with a gas reservoir (Figure 5:190). Column 7, lines 47-67 indicate that critical gases are moved to and from the culture chamber through the gas permeable membrane."

The Office further asserted:

> At the time of the invention, it would have been obvious to provide the Rajotte kit with an additional storage unit at the upper portion capable of serving as a gas reservoir. Prior to and following freezing, this additional reservoir would provide the cell culture with necessary critical gases required for growth and maintenance. Wilson teaches that the coupling of a gas reservoir to a cell culture compartment using a gas permeable membrane is well known in the art. Gas permeable membranes such as the one described in Wilson are formed from materials well known in the art, and could be incorporated into the Rajotte kit with only minor structural alteration.

Applicants respectfully traverse this rejection and submit that the Office has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. These requirements are summarized in the MPEP (MPEP §2143, and §2143.01 to §2143.03), *citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); and *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Even under KSR, the "key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." MPEP § 2141.III.

Applicants respectfully submit that cited combination of references does not teach or suggest the claimed device.

Claim 5 is directed to a self-contained cell culture vessel comprising a cell reservoir, a media reservoir distinct from the cell reservoir, and a gas reservoir; cells and a cryoprotectant containing medium disposed in said cell reservoir; a liquid cell culture medium disposed in said media reservoir in an amount capable of diluting the cryoprotectant to a volume suitable for cell growth, wherein thawing of the cryoprotectant containing medium and the liquid cell culture medium combines the cells, the cryoprotectant containing medium, and the liquid cell culture medium to provide a medium to culture the cells; and gas disposed in the gas reservoir.

As described in the previously filed Amendment, Rajotte teaches a method and apparatus for cryopreserving but not culturing biological material. (Abstract and Col. 2, lines 46-49). The cryopreservation devices comprise a bag having two laterally spaced separate and detachable compartments that provide an auxiliary cryopreservation storage until that can be used for viability testing. (*Id.*) This bag is shown in Figure 6. Rajotte states, "the freezer bag is specifically designed to allow known volumes of the preparation of tissue to be refluxed back from the main freezer bag into the two smaller side compartments." (Col. 4, lines 43-46). The side bags are removed for further testing. (Col. 4, lines 56-58).

In response to Applicants previous Amendment, The Office stated:

> "the internal chamber (Figure 6:4) of Rajotte is used as a media reservoir and a cell reservoir. Columns 3 and 4 indicate that a cryoprotectant, tissue samples, and a tissue culture medium are all added to the internal chamber for later processing. The claims do not require that the cell reservoir, media reservoir, and internal chamber are constructed as separate and independent chambers. In fact, Applicant indicates in Figure 1 of the drawings submitted 5/22/2006 that only a single chamber is used as a cell reservoir, media reservoir, and internal chamber." (OA at pages 11-12).

The Office's analysis relies on its analysis that the cell reservoir and media reservoir need not be separate chambers. Applicant agrees that the cell reservoir, media reservoir and internal chamber do not need to be separate and independent chambers. However, as reflected by the claims, the cell reservoir and media reservoir are separate and distinct components of the vessel in the claimed kit. For example, the cell reservoir may be a self-contained reservoir such as a gelatin capsule that contains the cell culture components. *See, e.g.,* paragraphs **[0045]**-**[0046]**. Even if the

liquid cell culture medium is contained in the internal chamber such that the media reservoir and internal chamber are the same structure, and the cells are in a capsule (the cell reservoir) that is also housed within the internal chamber, the cell reservoir is distinct from the liquid cell culture medium in the media reservoir since the contents of the cell reservoir are separate from the contents of the media reservoir. The two components of the claims are indeed separate and distinct (even if not independent chambers). Each embodiment described in the specification that contains both a media reservoir and a cell reservoir describes that the two are separate and distinct. *See e.g.*, paragraphs **[0045]-[0046], [0083]**, **[0087]**, and **[0089]-[0090]**. *In addition, this aspect is reflected in the claims.*

Figure 1 merely shows a top view of one embodiment. *See* paragraph **[0025]**. It does not refer to the cell reservoir or media reservoir at all. It is impossible to examine Figure 1, and determine whether or not the cell reservoir is separate or not separate from the media reservoir. One would need to look at other figures such as Figure 6 to understand the possible placement of said claimed features. Figure 6 shows that the cell reservoir (30) containing the cryoprotective media (32) and cells (99) is separate from the media reservoir (34).

In view of these comments, Applicants note that Rajotte's internal chamber (Figure 6:4) of Rajotte is not used as a media reservoir. Rajotte does not describe that the internal chamber contains a tissue culture medium in an amount capable of diluting the cryoprotectant to a volume suitable for cell growth upon thawing of the cryoprotectant containing medium and the liquid cell culture medium, where the thawing combines the cells, the cryoprotectant containing medium, and the liquid cell culture medium to provide a medium to culture the cells. Rajotte merely discloses that the cells are frozen in a cell culture medium that contains cryoprotectant. Applicants note that there is no motivation to increase the volume of tissue culture media in Rajotte's internal chamber to an amount capable of diluting the cryoprotectant to a volume suitable for cell growth upon thawing of the cryoprotectant containing medium since that would negate the efficacy of the cryopreservation process by decreasing the concentration of cryoprotectant. There is also nothing in Rajotte to indicate that the cryopreserved cells from the internal chamber may be cultured in Rajotte's apparatus without the addition of additional cell culture medium. This is supported by the

fact that cells are removed from Rajotte's apparatus and the cryoprotectant must be removed before the cells can be analyzed for viability.

Rajotte describes the process of thawing and using the frozen cells at Col. 3:66 – Col. 4, line 4 (emphasis added):

> When cryopreserved material is needed, it is retrieved from storage and rapidly thawed, e.g., at about 150° C. to 200° C./min 0° C., and then placed in an ice slush. The cryoprotectant is then removed either by sucrose or slow step dilution *before being transferred to isotonic media* and readied for in vitro viability testing or transplantation.

Rajotte thus explicitly describes that the cells and cryoprotectant that are transferred to the side compartment are treated to remove the cryoprotectant, and then the cells are transferred to isotonic media for further study *i.e.*, testing, culture or transplantation. Rajotte further describes the two processes in detail in Col. 7, lines 46 – Co. 8, line 5. When sucrose dilution is used, the freezer bag is drained into a separate centrifuge tube, and centrifuged. Sucrose and media are added to the tube in aliquots. Slow step dilution involves adding media to the bag containing the cells to dilute the concentration of the cryoprotectant.

Neither the internal chamber nor the side compartments contain media for diluting the cryoprotectant to a volume suitable for cell growth upon thawing of the cryoprotectant containing medium and the liquid cell culture medium. According to Rajotte, the media added to remove or dilute the cryoprotectant is separate from the internal chamber and the side compartment/freezer bags, and is separately added to the freezer bags prior to further processing. The media is thus not part of the self-contained apparatus. The claims require that the media in the media reservoir be part of the self-contained apparatus.

Accordingly, Rajotte does not teach a self-contained cell culture vessel and does not teach a media reservoir containing a liquid cell culture medium disposed in said media reservoir in an amount capable of diluting the cryoprotectant to a volume suitable for cell growth when combined with the cells and cryoprotectant from the cell reservoir upon thawing of the

cryoprotectant containing medium and the liquid cell culture medium, thereby providing a medium to culture the cells. As acknowledged by the Office, Rajotte also does not teach a gas disposed in a gas reservoir.

Wilson does not cure these deficiencies in Rajotte, other than teaching the use of gas exchange membranes.

The Office stated that Wilson was not cited to teach "the combination of a cryoprotectant with a cell culture medium. Rajotte already discloses this limitation. Wilson is merely relied on for teachings regarding the use of a gas reservoir in communication with a cell reservoir." (OA at page 12). Accordingly, the Office agrees that Wilson does not cure the deficiencies in Rajotte with respect to the claims other than teaching a gas reservoir in communication with a culture chamber.

To be clear, Applicants' previously noted that Wilson teaches a tissue culture flask comprising a cell culture compartment, a basal medium compartment, and a gas reservoir that is in communication with the culture chamber. Wilson's basal medium compartment does not satisfy the current claim requirement that the apparatus contain a media reservoir containing a liquid cell culture medium disposed in said media reservoir in an amount adapted to dilute the cryoprotectant to a volume suitable for cell growth when combined with the cells and cryoprotectant from the cell reservoir upon thawing of the cryoprotectant containing medium and the liquid cell culture medium. Wilson's basal medium compartment is separated from the cell culture compartment by a selectively permeable membrane for certain classes of molecules. (Col. 3, lines 1-4). The media contained in Wilson's basal medium compartment does not combine with cells and cryoprotectant in the cell culture compartment to dilute the cryoprotectant after thawing and thereby provide a medium for culturing the cells. Wilson does not even teach that the cells in its cell reservoir can contain cryoprotectant. Since Wilson's cells do not contain cryoprotectant, there is no motivation to include a media reservoir in Wilson's device that contains a liquid cell culture medium in an amount adapted to dilute the cryoprotectant in the cell reservoir when the contents of the two reservoirs are combined after thawing.

In the absence of a teaching or suggestion of each and every claim element, the cited combination fails render obvious claim 5 (and dependent claims). Thus, the claimed devices and methods are patentable over Rajotte in view of Wilson. Since neither Rajotte nor Wilson, alone or in combination, disclose every element of claim 5, Applicants respectfully request that the rejection of claims 5-10, 13, 15-18, 20, 22 and 25-27 under 35 U.S.C. § 103 be withdrawn.

Rajotte in view of Wilson and further in view of Mullen or Anderson

Claims 11 and 24 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Rajotte in view of Wilson as applied to claims 8 and 18, and further in view of Mullen (US 5679565). Claims 19, 21 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rajotte in view of Wilson as applied to claims 18 and 20, and further in view of Anderson (US 20060246490).

With respect to Mullen, the Office asserted:

> Mullen discloses a means for storing and preserving tissues that includes an internal compartment (Figure 1:12) serviced by a channel (Figure 1:28) for conveying fluids. Mullen teaches in column 5, lines 7-22 that a cell filter (Figure 1:22) is attached to the channel.
>
> At the time of the invention, it would have been obvious to provide the kit of Rajotte with a filter means at the inlet/outlet channel capable of retaining tissue cells within the kit while preventing the passage of contaminants. Filter means, as evidenced by Mullen, are considered to be well known in the cell culture art, and are beneficial because they serve to prevent contamination. The cell filter of Mullen would serve the additional advantage if incorporated into the Rajotte kit of maintaining stored tissue inside the reservoir, thereby preventing undesirable tissue loss during the removal of fluids.

With respect to Anderson, the Office asserted:

> Anderson discloses a substrate for measuring the presence of biochemical analytes in a sample solution. Anderson teaches in paragraph [0183] that ball valves are common means for controlling fluid motion in a channel. Anderson additionally teaches in paragraphs [0338] and [0339] that micro electro mechanical systems are likewise commonly used as valve means. . . .

> At the time of the invention, it would have been obvious to provide any known means for regulating fluid flow in the Rajotte device as a substitute for the mechanisms already disclosed by Rajotte. Anderson teaches that MEMS and ball valve structures are commonly implemented in microfluidic systems, and that each represents a functionally equivalent way to restrict fluid flow. Accordingly, it would have been obvious to implement these well known features in the Rajotte kit in order to predictably and effectively control the movement of fluid to and from the various reservoirs.

As described supra, neither Rajotte nor Wilson, alone or in combination, disclose every element of claim 5 (or its dependent claims). Neither of Mullen or Anderson cures this deficiency. None of these references teach or suggest a self-contained cell culture vessel nor do they teach or suggest a device having a media reservoir containing a liquid cell culture medium disposed in said media reservoir in an amount capable of diluting the cryoprotectant to a volume suitable for cell growth when combined with the cells and cryoprotectant from the cell reservoir, wherein thawing of the cryoprotectant containing medium and the liquid cell culture medium combines the cells, the cryoprotectant containing medium, and the liquid cell culture medium to provide a medium to culture the cells.

Since neither Rajotte nor Wilson, alone or in combination with Mullen or Anderson disclose every element of claim 5 (or its dependent claims), Applicants respectfully request that the rejection of claims 11, 19, 21, 23, and 24 under 35 U.S.C. § 103 be withdrawn.

CONCLUSIONS

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 220002067500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 8, 2009

Respectfully submitted,

By: /Elizabeth Cary Miller/
Elizabeth Cary Miller
Registration No.: 54,708
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
(858) 314-7717